



5. 510(k) Summary (21 CFR 807.92(a))

Date Prepared: January 7, 2012

MAY 23 2012

5.1 Submitted By:

Julia Yeh
Director
Corporate Quality & Regulatory Affair

Scandinavian Health Limited (SHL)
No. 136 Kuo Sheng 2nd Street
Taoyuan City, Taiwan 330, R.O.C

Phone: +1-240-367-5200

Fax: +1-800-887-6260

5.2 Name of Device:

Product name:	Push-On Needle
Common name:	Sterile disposable hypodermic needle
Regulation number:	880.5570
Classification name:	Needle, Hypodermic, Single Lumen
Class:	Class II
Product code:	FMI

5.3 Predicate Devices:

Device name: NovoTwist[®] 30G X 8 mm needle,

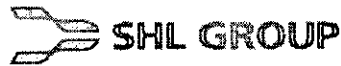
510(k) number: K093109

Device name: Feel Fine[®] Insulin Pen Needle

510(k) number: K080904

5.4 Substantial Equivalence

The Push-On Needle is substantially equivalent to the Feel Fine[®] Insulin Pen Needle and NovoTwist[®] needle. Proof of substantial equivalence is supported by the attached documentation.



5.5 Device Description

The Push-On Needle is a sterile, non-pyrogenic, single-use, pen needle designed for use with a compatible auto-injector. The Push-On Needle consists of a 30G×8 mm stainless steel cannula, plastic hub, plastic shield and a protective sealing paper. The assembled Push-On Needle has a circular hub design that clicks and attaches to a cartridge retainer ridge of an auto-injector. Push-On Needle is used by peeling the sealing paper, thus exposing the non-patient end of the needle and pushing this end up against the auto-injector nozzle, and then attaching the needle hub to the auto injector nozzle. The needle shield can be pulled off making the Push-On Needle ready to use.

5.6 Intended Use

The Push-On Needle is intended for the hypodermic injection of fluids into the body when attached to a compatible auto-injector.

5.7 Technological Characteristics

The Push-On Needle has similar technological characteristics as the Feel Fine® Insulin Pen Needle and NovoTwist® needle. Minimal differences between the devices do not raise any significant new issues regarding safety and effectiveness.

5.8 Performance and Safety Data

The Push-On Needle has been designed and tested to meet requirements of voluntary standards and FDA guidance documents applicable to the subject device and predicate devices. Results of non-clinical testing support the substantial equivalence of Push-On Needle to the named predicate devices.

Performance Testing:

The Push-On Needle has met the requirements outlined in ISO 7864 and ISO 9626. Additional performance tests included (paper seal) peel resistance (ASTM F2824) and (needle) cover (i.e. shield) pull off force (internal standard).

Biocompatibility Testing:

The materials of Push-On Needle have successfully passed testing as outlined in ISO 10993-1 for devices categorized as External Communicating Devices, Circulating Blood, Limited Exposure.



Sterilization and Shelf-life Testing:

The sterility of Push-On Needle is assured by using a validated sterilization method qualified in accordance with AAMI TIR 33:2005. The needles are sterilized by gamma irradiation and have a sterility assurance level (SAL) of 10^{-6} .

The shelf-life testing of Push-On Needle has been performed in accordance with ISO 11607-1:2006

Clinical Data

No clinical tests are required.

5.9 Conclusion

The intended use, principle of operation, technology, materials, performance of Push-On Needle and the predicate devices, K093109 and K080904, are essentially the same. The minor differences between the devices do not raise any significant issues of safety or efficacy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ms. Sharlin Yeh
Vice President
Scandinavian Health Limited (SHL)
No. 136 Kuo Sheng 2nd Street
Taoyuan City, 330
Taiwan

MAY 23 2012

Re: K120191
Trade/Device Name: Push-On Needle 30GX 8mm
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 16, 2012
Received: May 17, 2012

Dear Ms. Yeh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

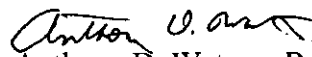
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120191



Indications for Use

510(k) Number (if known): Not available

Device Name: Push-On Needle 30G×8 mm

Indications for Use:

Push-On Needle is intended for hypodermic injection of fluids into the body when attached to a compatible auto injector.

Prescription Use _____ AND/OR
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use ✓
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120191